

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

ANDREA CAMERON, et al.,)	CASE NO. 1:10 CV 2258
)	
Plaintiff,)	
)	
v.)	JUDGE DONALD C. NUGENT
)	
BOSTON SCIENTIFIC CORP.,)	Magistrate Judge William H. Baughman, Jr.
)	
Defendant.)	<u>MEMORANDUM OPINION</u>

This matter is before the Court upon the Report and Recommendation of Magistrate Judge William H. Baughman, Jr. (Document #20.) The Magistrate Judge recommends that the Motion for Summary Judgment filed by Defendant, Boston Scientific Corporation, be granted.

Factual and Procedural History

As set forth by the Magistrate Judge, the factual and procedural history of this case is as follows:

The facts relevant to the present motion are not extensive, and, as required, the Court must view those facts in the light most favorable to the Camerons. But, as will be more fully detailed below, critical portions of the plaintiffs' claims remain merely allegations without evidentiary support in the Rule 56 record.

The case involves a claim for damages arising from the use of a HydroThermAblator (HTA); a Class III medical device designed, manufactured, and sold by BSC under regulations administered by the United States Food and Drug Administration (FDA). BSC designed the HTA device to circulate heated

saline in the uterus to eliminate or reduce menstrual bleeding, a minimally invasive alternative to a hysterectomy. The process, under the supervision of a physician, requires that: (a) the HTA sheath be inserted and sealed into the uterine cavity; (b) then saline circulates through the sheath and into the uterine cavity at increasing heat, ultimately reaching 90 degrees Celsius, which temperature is maintained for ten minutes; and finally (c) room temperature saline is used to flush and cool the treated area.

Andrea Cameron received HTA treatment from her physician as an out-patient at the Cleveland Clinic in 2008. She alleged that her procedure “did not go as specified” by BSC in its literature. In particular, the complaint asserts that during “the heating and circulation phase of the procedure, the HTA malfunctioned and began leaking hot fluids,” resulting in burns to Cameron’s “vaginal introitus, her outer vaginal area, and buttocks.”

For its part, BSC states that “[o]ne of the risks associated with this procedure is a potential for leakage of hot fluid, which may result in thermal injury to surrounding tissue.” To that point, BSC states that the HTA System User’s Manual and other literature explains this risk to patients. It also states that the FDA, through the pre-market approval (PMA) process, as well as the requirement for continued reporting of “adverse events,” has full responsibility for regulating the manufacture, sale, and marketing of the HTA device here. Thus, it contends, under the Medical Device Amendments (MDA) of 1976, as interpreted by the Supreme Court, the Camerons’ claims are preempted and that the Court should grant summary judgment for BSC.

The Camerons, while agreeing that federal regulations govern the design, manufacture, and use of the HTA, assert that because BSC failed to comply with those regulations, the claims are not preempted. In particular, the complaint alleges that in January 2009, BSC recalled certain HTA units for a defect in the circuit board that could result in a failure of the system pump leading to patient injury from hot fluid leaks during the recirculating/heating phase of treatment. The complaint further maintains that the stated grounds for this recall are “consistent” with what happened to Andrea Cameron, and so BSC, in effect, failed to follow controlling federal regulations by not recalling the HTA unit used for Andrea Cameron’s procedure.

Report and Recommendation (Docket #20) at pp.2-4. (Citations omitted.)

On January 11, 2011, Defendant filed its Motion for Summary Judgment pursuant to Fed. R. Civ. P. 56(b). (Docket #15.) On February 10, 2011, Plaintiffs filed their Response to Defendant’s Motion for Summary Judgment. (Docket #17.) On February 24, 2011, Defendant

filed a Reply Brief. (Docket #18.)

Report and Recommendation

On April 12, 2012, the Magistrate Judge issued his Report and Recommendation, recommending that the Motion for Summary Judgment filed by Defendant be granted. The Magistrate Judge noted that although *pro se* plaintiffs are to be accorded leniency, such leniency “is not boundless.” *Martin v. Overton*, 391 F.3d 710, 713 (6th Cir. 2004). The Magistrate Judge determined that while Plaintiffs’ claim was unlikely to be preempted, as was argued by Defendant, Plaintiffs failed to support their allegations with evidence. The Magistrate Judge noted that Plaintiffs conducted no discovery under the case management plan filed in this case, despite being informed at the initial Case Management Conference that Defendant planned to file a dispositive motion; that Plaintiffs failed to participate in the telephone status conference held immediately after Defendant filed its Motion for Summary Judgment; and, that Plaintiffs’ Response to Defendant’s Motion for Summary Judgment contained no Rule 56 evidence of any kind.

No objections were filed to the Report and Recommendation.

Standard of Review for a Magistrate Judge’s Report and Recommendation

The applicable standard of review for a magistrate judge’s report and recommendation depends upon whether objections were made to that report. When objections are made to a report and recommendation of a magistrate judge, the district court reviews the case de novo. FED. R. CIV. P. 72(b) states:

The district judge must determine de novo any part of the magistrate judge's disposition that has been properly objected to. The district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions.

The text of Rule 72(b) addresses only the review of reports to which objections have been made; it does not indicate the appropriate standard of review for those reports to which no objections have been properly made. The Advisory Committee on Civil Rules commented on a district court's review of *unopposed* reports by magistrate judges. In regard to subsection (b) of Rule 72, the advisory committee stated: "When no timely objection is filed, the court need only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation." FED. R. CIV. P. 72 advisory committee's notes (citation omitted).

The U.S. Supreme Court stated in *Thomas v. Arn*, 474 U.S. 140, 150 (1985): "It does not appear that Congress intended to require district court review of a magistrate judge's factual or legal conclusions, under a de novo or any other standard, when neither party objects to those findings."

Conclusion

This Court has reviewed the Magistrate Judge's Report and Recommendation. After careful evaluation of the record, this Court adopts the findings of fact and conclusions of law of the Magistrate Judge as its own. Summary judgment is appropriate based upon Plaintiffs' failure to present any evidence in support of their claims.

Accordingly, the Report and Recommendation (Docket #20) is ADOPTED. The Motion for Summary Judgment filed by Defendant (Docket #15) is GRANTED.

IT IS SO ORDERED.

s/Donald C. Nugent
DONALD C. NUGENT
United States District Judge

DATED: May 3, 2012